In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: October 2, 2020

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| ASHLEY MULLER, | * | UNPUBLISHED |
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| Petitioner, | * | No. 18-1258V |
| | * | |
| v. | * | Special Master Dorsey |
| | * | |
| SECRETARY OF HEALTH | * | Petitioner's Motion for Decision Dismissing |
| AND HUMAN SERVICES, | * | Her Petition; Human Papillomavirus |
| , | * | ("HPV") Vaccine; Dysautonomia. |
| Respondent. | * | |
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<u>Andrew D. Downing</u>, Van Cott & Talamante, PLLC, Phoenix, AZ, for petitioner. <u>Kimberly S. Davey</u>, United States Department of Justice, Washington, DC, for respondent.

DECISION¹

On August 21, 2018, Ashley Muller ("petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program ("Vaccine Program")² alleging that as a result of the human papillomavirus ("HPV") vaccinations administered on August 28, 2015, October 27, 2015, and March 14, 2016, she suffered dysautonomia. Petition at 1, 9 (ECF No. 1). On September 8, 2020, petitioner moved for a decision dismissing her case.

After reviewing the medical records, expert reports, and all of the information in the record, the undersigned finds petitioner has failed to establish that she has sustained a vaccine-related injury.

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¹ Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

² The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 et seq. (hereinafter "Vaccine Act" or "the Act"). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

I. PROCEDURAL HISTORY

On August 21, 2018, petitioner filed a petition along with an affidavit. Petition (ECF No. 1); Petitioner's Exhibit ("Pet. Ex.") 1. Petitioner filed medical records between September 2018 and March 2019. Pet. Exs. 2-14. On April 25, 2019, respondent filed his Rule 4(c) Report, recommending against compensation. Respondent's Report ("Resp. Rept.") at 1 (ECF No. 20). Thereafter, additional records were filed in June and July 2019. Pet. Exs. 15-16. On September 20, 2019, petitioner filed an expert report from Dr. Harpreet Pall. Pet. Ex. 17.

This case was reassigned to the undersigned on October 10, 2019. Notice of Reassignment dated Oct. 10, 2019 (ECF No. 30). From December 2019 to January 2020, petitioner filed additional medical records. Pet. Exs. 19-28. Respondent filed an expert report from Dr. Jeffrey R. Boris on February 13, 2020, and on March 2, 2020, respondent filed an expert report from Dr. Chris Liacouras. Resp. Exs. A, GG.

In a joint status report filed on April 15, 2020, the parties requested a Rule 5 conference. Joint Status Rept., filed Apr. 15, 2020 (ECF No. 53). The Rule 5 conference was scheduled for May 7, 2020; however, the undersigned was unable to provide her preliminary opinions after reviewing the medical records and expert reports. Order dated May 7, 2020, at 1 (ECF No. 54). Petitioner was ordered to file a responsive expert report and/or an additional expert report, along with updated medical records. <u>Id.</u> at 1-2. Petitioner filed updated medical records in July and August 2020. Pet. Exs. 40, 43.

On September 8, 2020, petitioner moved for a decision dismissing her case, stating that "she would like to opt out of the Vaccine Program . . . to pursue a third party action in district court against Merck directly." Petitioner's Motion for a Decision Dismissing Her Petition, filed Sept. 8, 2020, at \P 3 (ECF No. 62). Petitioner states that she understands that a decision by the Special Master will result in a judgment against her, and that she has been advised that such judgment will end all of her rights under the Vaccine Act. <u>Id.</u> at \P 4. Petitioner states that she intends to protect her right to file a civil action and to elect to reject the Vaccine Program judgment to file a civil action. <u>Id.</u> Respondent filed a status report stating that respondent does not object to petitioner's motion. Resp. Status Rept., filed Sept. 8, 2020 (ECF No. 64).

II. ANALYSIS

To receive compensation under the Program, petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to the vaccination, or (2) that she suffered an injury that was actually caused by the vaccination. See §§ 11(c)(1), 13(a)(1)(A). The records submitted by petitioner show that she does not meet the statutory requirement under 42 U.S.C. § 300aa-11(c)(1)(D)(i) to establish entitlement to compensation. The Federal Circuit has explained that the eligibility requirements in Section 11(c) are not mere pleading requirements or matters of proof at trial, but instead are "threshold criteri[a] for seeking entry into the compensation program." Black v. Sec'y of Health & Hum. Servs., 93 F.3d 781, 785-87 (Fed. Cir. 1996).

In this case, the experts disagree about petitioner's diagnosis. Petitioner's expert, Dr. Pall, opines petitioner suffers a dysautonomia due to vaccination. Specifically, he finds petitioner's complaints and symptoms are similar to others who experience dysautonomia post-HPV vaccination. Additionally, although petitioner was never tested for Postural Orthostatic Tachycardia Syndrome ("POTS"), he believes she could suffer from POTS because her symptoms are suggestive of autonomic dysfunction.

On the other hand, respondent's experts, Drs. Boris and Liacouras, disagree with petitioner's expert's diagnosis and etiology. They opine petitioner does not suffer from POTS, the HPV vaccine did not cause petitioner's symptoms, and likely one of the various alternative causes, including an infection, caused petitioner's symptoms.

Dr. Boris opines petitioner could have one of the functional gastrointestinal disorders, which can be considered to be a form of dysautonomia; however, specific imaging and testing would need to be done to confirm or rule out these diagnoses. Dr. Boris further notes there can be multiple etiologies to which petitioner's symptoms can be attributed that are not autonomic in nature, including infection, like the UTI petitioner had 10 days prior to her first HPV vaccination. He also opines that even if diagnostic testing for POTS was performed, petitioner likely would not have been diagnosed with POTS.

Dr. Liacouras opines that there is evidence petitioner suffered from an autoimmune disorder years prior to her first HPV vaccination. He agrees with Dr. Boris that petitioner's symptoms are more likely due to an alternative cause.

III. CONCLUSION

The undersigned has reviewed the medical records, expert reports, and all of the information in the record, and finds petitioner has failed to establish that she has sustained a vaccine-related injury by preponderant evidence.

Accordingly, in light of petitioner's motion and a review of the record, the undersigned finds that petitioner is not entitled to compensation. Thus, this case is dismissed. The Clerk shall enter judgment accordingly.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master